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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|---|-------------|----------------------|------------------------|------------------|--|
| 09/445,289 | 05/11/2000 | GALINA V MUKAMOLOVA | 49946-60261 | 9774 | |
| 7590 EDWARDS ANGELL PALMER & DODGE LLP P.O. BOX 55874 | | | EXAM | EXAMINER | |
| | | | DEVI, SARVAMANGALA J N | | |
| BOSTON, MA 02205 | | | ART UNIT | PAPER NUMBER | |
| | | | 1645 | | |
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| | | | MAIL DATE | DELIVERY MODE | |
| | | | 05/18/2010 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief

| Application No. | Applicant(s) | |
|-----------------|-------------------|--|
| 09/445,289 | MUKAMOLOVA ET AL. | |
| Examiner | Art Unit | |
| S. Devi, Ph.D. | 1645 | |

| | S. Devi, Fil.D. | 1045 | | | | | | |
|---|--|--|----------------------|--|--|--|--|--|
| The MAILING DATE of this communication appe | ars on the cover sheet with the o | correspondence add | ress | | | | | |
| THE REPLY FILED 05052010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. | | | | | | | | |
| 1. The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods: | | | | | | | | |
| a) \(\bigcirc \) The period for reply expires \(\frac{four}{u} \) months from the mailing date of this A no event, however, will the statutory period for reply expire to Examiner Note: If box 1 is checked, check either box (a) or (| dvisory Action, or (2) the date set forth ater than SIX MONTHS from the mailing | date of the final rejection | n. | | | | | |
| MONTHS OF THE FINAL REJECTION See MPEP 706.07(f) Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filled is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action, or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filled, may reduce any seamed patient term adjustment. See 37 CFR 1.704(b). NOTICE OF APPEAL | | | | | | | | |
| The Notice of Appeal was filed on A brief in comp filing the Notice of Appeal (37 CFR 41.37(a)), or any exter Notice of Appeal has been filed, any reply must be filed with the property of the pr | sion thereof (37 CFR 41.37(e)), to | avoid dismissal of the | | | | | | |
| <u>AMENDMENTS</u> | | | | | | | | |
| ∑ The proposed amendment(s) filed after a final rejection, t (a)∑ They raise new issues that would require further co (b)∑ They raise the issue of new matter (see NOTE below (c)∑ They are not deemed to place the application in better the contraction of the contrac | nsideration and/or search (see NOT w); | ΓE below); | | | | | | |
| appeal; and/or (d) ☐ They present additional claims without canceling a c | | ected claims. | | | | | | |
| NOTE: See Continuation Sheet. (See 37 CFR 1.1 | | | | | | | | |
| 4. The amendments are not in compliance with 37 CFR 1.12 | | mpliant Amendment (| PTOL-324). | | | | | |
| Applicant's reply has overcome the following rejection(s): Newly proposed or amended claim(s) would be all non-allowable claim(s). | | timely filed amendmer | nt canceling the | | | | | |
| 7. \(\times\) For purposes of appeal, the proposed amendment(s); a) I how the new or amended claims would be rejected is prov. The status of the claim(s) is (or will be) as follows: Claim(s) allowed: \(\times\)(\time | ided below or appended. | l be entered and an e | xplanation of | | | | | |
| AFFIDAVIT OR OTHER EVIDENCE | | | | | | | | |
| The affidavit or other evidence filed after a final action, but because applicant failed to provide a showing of good and was not earlier presented. See 37 CFR 1.116(e). | | | | | | | | |
| The affidavit or other evidence filed after the date of filing entered because the affidavit or other evidence failed to o showing a good and sufficient reasons why it is necessary | vercome <u>all</u> rejections under appea and was not earlier presented. Se | al and/or appellant fail se 37 CFR 41.33(d)(1 | s to provide a). | | | | | |
| The affidavit or other evidence is entered. An explanation REQUEST FOR RECONSIDERATION/OTHER | n of the status of the claims after er | ntry is below or attach | ed. | | | | | |
| 11. The request for reconsideration has been considered but | does NOT place the application in | condition for allowan | ce because: | | | | | |
| 12. Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s) 13. Other: | | | | | | | | |
| | | | | | | | | |

Continuation of 3 NOTE:

- 1) The dependent claim 128, as amended, includes the new limitations: 'said bacterial cell is' and by detecting growth of bacterial cells in the sample,' which were not previously presented. These limitations raise new indefiniteness issues, requiring further consideration under 35 U.S.C.§ 112, second paragraph, since the claim is inconsistent in the use of pleural and non-pleural limitations: 'said bacterial cell in present in a sample,' a. ... bacterial cell in the sample; and by detecting growth of 'bacterial cells in the sample.' Claim 128, as amended, further lacks proper antecedent basis in the limitation 'bacterial cells in the sample and bacterial cells in the sample is in the sample is a manufactural cells in the sample is in the sampl
- 2) Claim 144, as amended, includes the new limitation: 'the bacterial cell' ... thereby resuscitating said cells, which was not previously presented. The limitation raises a new indefiniteness issue, requiring further consideration under 35 U.S.C § 112, second paragraph, since the claim is inconsistent in the pleural and non-pleural limitations: 'the bacterial cells in vitro', 'incubating the bacterial cell' and 'thereby resuscitating said cells'.
- 3) The dependent new claim 162 includes the inconsistent pleural and non-pleural limitations: 'said bacterial cells ... in a sample' and 'identifies a ... bacterial cell in the sample by detecting growth of bacterial cells in the sample, which were not previously presented. The limitation 'bacterial cells in the sample' is improperly broadening in scope compared to the narrower limitation 'Mycobacterium tuberculosis bacterial cells' recited in the base claim. These limitations raise new indefiniteness issues, requiring further consideration under 35 U.S.C.§ 112, second paragraph.
- 4) The new limitations in claims 128 and 162: 'the method identifies ... bacterial cell by detecting growth of bacterial cells in the sample' encompass identifying by detecting the growth of the bacterial cells in the sample without the use of an indicator, label, or a dye. Such a method lacks descriptive support in the specification, as originally filed, and raises a new matter issue, requiring further consideration at least under 35 U.S.C.§ 112, first paragraph.

/S. Devi/ Primary Examiner AU 1645

May, 2010